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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/30/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/085,703

Applicant(s)

POLYAKOV ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/256925.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4 sheets
- 2) ☐ Notice of Draftsperson's Patent Rights (PDA) (PTO-893)
- 3) ☐ Information Disclosure Statement (PDA) (PTO-894)
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 2

## DETAILED ACTION

1. Applicants should update the status of all related applications; 09/256915 is now abandoned.

2. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to a dermatomycosis vaccine comprising the inactivated dermatophytes as set forth in claim 1 (8 dermatophytes) and as set forth in claim 2 (3 dermatophytes).

Applicants' representative (telephone conversation with Susan Pocchiari on May 24, 2002) has indicated that the vaccine must have all of the recited strains as set forth in claims 1 and 2. Examples 1-3 and Tables 9-10 have been reviewed. It is not clear what Applicants used in the vaccine composition. Example 1, page 18 indicates that "[A]fter 2 days, 125 ml of each culture in suspension is taken and mixed in a single container. The vaccine may be prepared by mixing together various combinations of the given strain." Exactly what was the composition of the vaccine administered that gave the results found in Tables 9 and 10? It is not clear if all 8 dermatophytes were used or some combination of 3, 4, 6 or 7 dermatophytes. It is not clear that the specific combination of 3 dermatophytes

was used in the vaccine composition. The specification does not disclose the specific combination of 3 dermatophytes used in the vaccine composition.

Applicants have not provided any evidence to show that the vaccine composition was used in the vaccine composition.

Applicant intend for "immunogenic response" to mean that vaccine protection has been established, see page 11?

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability

matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is

advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sarkisov (Mikol Fitopatol, 1985, 19/1:51-57). Abstract only

Sarkisov teaches a vaccine comprising an inactivated dermatophytes (*T. verrucosum*) or a combination of dermatophytes (*T. verrucosum* and *T. mentagrophytes*); data were presented on the formation of immunity in animals with trichophytosis and on vaccines against trichophytosis in cattle, horses and fur animals. It is noted that the prior art does not teach the use of the third dermatophyte as claimed in claim 2. However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a combination of dermatophytes to protect against multiple fungal infections. The art does suggest the use of more than one dermatophyte in the vaccine composition. The prior art teaches these inactivated dermatophytes and they are used for the same purpose as claimed by applicants, as a vaccine. The animals immunized are protected against dermatophyte infection. The claimed invention is prima facie obvious in view of the prior art absent any convincing evidence to the contrary.

over Werner et al.

Werner et al teach a ringworm vaccine that contains antigenic material from at least one dermatophyte and a suitable carrier, and that the antigen can be isolated from more than one dermatophyte (abstract). Werner et al teach a method of producing the vaccine (abstract). Werner et al also teach that when more than one dermatophyte is used as the antigen that it can include antigens which are common to all species of dermatophytes employed and/or antigens which are only to certain species (abstract). Werner et al teach that mammals are plagued by ringworm, dermatomycosis, which is caused by parasitic fungi generically referred to a dermatophyte (p. 2, l. 13-16). Table I list dermatophytes and their hosts. Werner et al teach a process of producing the dermatomycosis vaccine and a method of treatment of a patient for the purpose of producing immunity to ringworm infection or for the purpose of eradicating the existing infection (p. 5, l. 17-23 and examples 1-4). Werner et al teach the use of formaldehyde to inactivate or kill the dermatophytes (p. 5, l. 5-12). Werner et al teach a physiologically suitable carrier in the form of Ringers Solution and aluminum hydroxide gel (pp. 4-6, examples 1-4). Werner et al does not specifically teach the use of the specific dermatophytes as claimed.

However, It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the various dermatomycosis microorganisms for the expected benefit of obtaining a dermatomycosis vaccine. Werner et al teach the preparation of a dermatomycosis vaccine that comprise antigenic material from one or more of the dermatophytes. It is well known that the administration of a vaccine containing antigenic material of a pathogenic microorganism results in an increased immunity and resistance to infection by dermatophytes. Werner et al. describes the use of one

or a multiple of dermatophytes as the antigen in the vaccine and lists various species of dermatophytes (see Table I and claims 2 and 12) that could be used as antigen. Werner et al teaches the concept of a universal vaccine for the treatment of dermatomycosis. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use any dermatophyte in the vaccine composition that is known to contain antigenic material and be able to dermatomycosis and elicit an immune response. The reference teaches a vaccine composition having more than one dermatophyte. The claims are drawn to the strains with no specific characteristics and/or features. The claimed invention is prima facie obvious to a person of ordinary skill in the art at the time the invention was made over Werner et al, absent any convincing evidence to the contrary.

8. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pier ('904 or '652).

Pier ('904), for example, teaches a vaccine (and the preparation of a vaccine) for the prophylaxis or dermatophyte infection in animals using *T. mentagrophytes*, *M. canis*, and *M. gypseum* (abstract; claims; col. 3, l.43 to col. 8, l. 58; examples). Pier teaches a novel, broad spectrum vaccine for vaccination of cats, dogs, livestock and fur-bearing animals against contagious infections caused by dermatophytes (col. 1). Pier does not specifically teach the use of the specific dermatophytes as claimed.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the various dermatomycosis

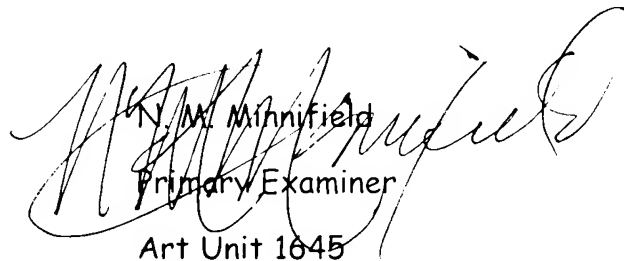
microorganisms for the expected benefit of obtaining a dermatomycosis vaccine. The art suggests a broad spectrum vaccine using multiple dermatophytes. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the antigenic material from the various dermatomycosis microorganisms for the expected benefit of obtaining a dermatomycosis vaccine. Pier teaches the preparation of a dermatomycosis vaccine that comprise antigenic material from one or more of the dermatophytes; therefore it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use these methods and components to prepare a dermatomycosis vaccine as claimed. Pier ('904) teaches methods of treatment using the vaccine for prophylaxis, increased immunity, or resistance to infection by dermatophytes. Pier ('904) describes the use of one or a multiple of dermatophytes as the antigen in the vaccine. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use any dermatophyte in the vaccine composition that is known to contain antigenic material and be able to dermatomycosis and elicit an immune response. The prior art teaches the concept of a universal vaccine for the treatment of dermatomycosis. The claimed invention is prima facie obvious to a person of ordinary skill in the art at the time the invention was made over Pier ('904), absent any convincing evidence to the contrary.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
N. M. Minnifield  
Primary Examiner  
Art Unit 1645

nmm